K 123573

510(K) SUMMARY

APR 1 5 2013

Introduction:

This document contains the 510(k) Summary for the YOULASER CO2 laser system.
The content of this summary is based on the requirements of 21 CFR 807.92(c).

Applicant / Manufacturer Name and Address:	Quanta System SPA Via IV Novembre, 116 Solbiate Olona (VA) Italy, 21058
510(k) Contact Person:	Maurizio Bianchi Regulatory Affairs Manager Quanta System SPA Email: Maurizio.bianchi@quantasystem.com Phone: +39-0331-376797 Fax: +39-0331-367815

Date Prepared:	November 16th, 2012
Device Name:	YOULASER CO2
Classification:	Class II
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation Number:	21 CFR 878.4810
Product Code:	GEX

Predicate Devices:

The YOULASER CO2 Laser System is claimed to be substantially equivalent to the following legally marketed predicate devices:

Lutronic Corp – MOSAIC e CO2 (K080496)
Lutronic Corp – MOSAIC e CO2 (K091115)
Lasering Srl – SLIM Evolution Family (K063001)
Lasering Srl – SLIM Evolution II Family (K110984)
El.En S.p.A - Smart CO2 Laser System (K072159)

Performance Standards:
There are no mandatory performance standards for this device.
A specific investigation to evaluate the safety and the effectiveness has been planned and performed :
A specific non clinical testing was conducted on the proposed YOULASER CO2 device to support a determination of substantial equivalence
The testing has evaluated the ablation, coagulation depth and the healing evolution of the skin at the typical settings of use of Youlaser CO2.
In conclusion the results of these tests provided reasonable assurance that the YOULASER CO2 is as safe as effective as the predicated devices and support a determination of substantial equivalence.

General Device Description:

The YOULASER CO2 Laser System includes a single model named YOULASER CO2 emitting a maximum power of 30 Watt at 10.6 µm.

The YOULASER CO2 Laser is composed externally of a metallic shell with a frontal polyurethane panel containing the touch screen display. On this panel the key switch, emergency red push button and the operation led are inserted too. On the rear panel the footswitch connector, the remote interlock, the power switch are located.

The laser system is composed of power supply, CO2 laser source with air cooling system, optical bench, articulated arm with CO2 scanner, the control electronics.

The electronic, based on a microcontroller, manages the voltage power supply and the CO2 laser source.

Indications for Use:

YOULASER CO2 laser when used in traditional, non fractionated mode is indicated for:
incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in medical specialties including aesthetic (dermatology and plastic surgery), otorhinolaryngology (ENT), gynaecology, neurosurgery, dental and oral surgery and genitourinary surgery.

YOULASER CO2 laser when used in fractionated mode (dot scanner) is indicated only for ablative skin resurfacing.

Comparison of Technological Characteristics:

The laser specifications for the YOULASER CO2 laser system are substantially equivalent to the laser specifications for its identified predicate device with respect to the laser source, wavelengths, maximum energy, spot size, fluence,

pulse width, repetition rate, beam delivery, power monitor, actuator, and aiming beam.

Comparison of Intended Use:

The intended use of the YOULASER CO2 laser system is the same as the intended use of its previously cleared devices.

Substantial Equivalence:

The Quanta System YOULASER CO2 laser system is as safe and effective as the predicate devices.
The YOULASER CO2 laser system has the same intended use and similar technological characteristics and principles of operation as its predicate devices. The minor technological differences between the YOULASER CO2 laser system and its predicate devices raise no new issues of substantial equivalence or safety and effectiveness.
Thus, the YOULASER CO2 laser system is substantially equivalent to its identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 15, 2013

Quanta System, S.P.A.
% Mr. Maurizio Bianchi
Via IV Novembre, 116
Solbiate Olona (VA)
Italy, 21058

Re: K123573
Trade/Device Name: YOULASER CO2
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: March 8, 2013
Received: March 11, 2013

Dear Mr. Bianchi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): **K123573**

Device Name: **YOULASER CO2**

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Prescription Use __X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
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(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number _K123573 _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR

Peter D. Rumm -S
2013.04.15 15:09:29
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(Division Sign-Off) for MXM
Neil R. Ogden, M.S.
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